

Serious Adverse Blood Reactions and Events (SABRE)

User guide for mandatory haemovigilance reporting in the UK

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Overview

The Department of Health has designated the Medicines and Healthcare products Regulatory Agency (MHRA) as the UK Competent Authority for blood safety. It is, therefore, the MHRA's responsibility to ensure there is an accessible mechanism for the reporting and recording of serious adverse blood reactions and events. To facilitate this reporting requirement the MHRA has developed SABRE, an online system that allows the drafting, editing, saving and submission of notifications and subsequent confirmations of blood related adverse events and adverse reactions.

1 WHY – the legal framework in the UK

1.1 UK legislation and the EU blood safety and quality directives

The Blood Safety and Quality Regulations 2005 No. 50 [1] and the Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898 [2] became effective for the purposes of regulation in the United Kingdom (UK) on 08 November 2005. These regulations implement the requirements of the following European Union (EU) directives:

- Directive 2002/98/EC [3] – setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
- Directive 2004/33/EC [4] – regarding certain technical requirements for blood and blood components.

Two further technical directives were adopted by the European Commission on 30 September 2005. These are:

- Directive 2005/61/EC [5] regarding traceability requirements and notification of serious adverse reactions and events
- Directive 2005/62/EC [6] regarding community standards and specifications relating to a quality system for blood establishments.

These directives were transposed into UK legislation by the Blood Safety and Quality (Amendment) Regulations 2006 No. 2013 [7], which came into force on 31 August 2006.

The Blood Safety and Quality Regulations [7] apply to **blood establishments** and to **hospital blood banks**. The 2006 Amendment Regulations [7] introduce requirements for a quality system in blood establishments and hospital blood banks. They also extend traceability and record-keeping requirements to 'facilities' which may receive blood and blood components (care homes, independent clinics, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research.)

1.2 Reporting to the MHRA

Directive 2005/61/EC [5] introduces the legal requirement for serious adverse reactions (SARs) and serious adverse events (SAEs) occurring within EU member states to be reported to the relevant Competent Authority. The Department of Health has designated the MHRA as the UK Competent Authority. It is, therefore, the MHRA's responsibility to provide a mechanism for the reporting and recording of

these incidents. For this purpose the MHRA has developed the fully accessible online reporting system: SABRE (Serious Adverse Blood Reactions & Events).

Haemovigilance comprises organised surveillance procedures relating to serious adverse or unexpected events or reactions in blood donors or recipients, and the epidemiological follow-up of donors. The overall aim of this is to improve transfusion safety. The UK was one of the first countries to implement such a system and since 1996 the Serious Hazards of Transfusion (SHOT) scheme has successfully undertaken those aspects of haemovigilance relating to recipients. Implementation of the Directive 2005/61/EC [5] with the **mandatory** requirement for reporting to the MHRA has provided an opportunity to strengthen and further develop haemovigilance in the UK.

This document describes the requirements of the directives and also, in order to assist reporters of adverse events and reactions, includes guidance and flow charts to help identify what constitutes a serious adverse reaction and a serious adverse event and, therefore, what is or is not reportable to the Competent Authority (MHRA) under the Directive 2005/61/EC [5] and UK legislation [7]. However, this does not provide a definitive list of what does and what does not constitute a reportable incident. You may also need to contact the MHRA for advice. As a general rule, in cases of doubt, a report should be submitted.

1.3 Annual summary reports

Article 8 of Directive 2005/61/EC [5] and UK legislation [7] requires the Competent Authority to submit an annual report to the Commission, by 30 June of each year. The MHRA SABRE team will therefore ask each reporter to review and verify a summary of their reports for the preceding calendar year **by the end of March the following year**. For example, we will ask you to verify the summary of your 2010 reports by the end of March 2011. In order to provide an accurate record of overall transfusion activity in the UK you will be asked to submit data in the format shown in the table below.

Report related to	SABRE summary report confirmed as accurate	Number of units issued	Number of recipients	Number of units transfused
Whole blood	Yes/No			
Red blood cells	Yes/No			
Platelets	Yes/No			
Plasma (Including cryo precipitate)	Yes/No			
Other (include granulocytes and buffy coats, but not blood products such as anti-D etc)	Yes/No			
Events	Yes/No			

Notes

Number of units issued = units distributed by blood establishments to the hospital blood banks + units issued by blood establishments directly for transfusion.

Number of recipients transfused = overall number of recipients transfused at least once over a period of one year.

Number of units transfused = the total number of individual units transfused over the reporting period independent of the number of hospitalisation episodes but including home transfusions.

1.4 Annual haemovigilance fees

Under the terms of The UK Blood Safety and Quality (Amendment) (No. 2) Regulations 2005 [2], paragraph (3B), the person who is responsible for the management of a hospital blood bank is required by law to ensure that the annual haemovigilance fee is paid to the Finance Division of the MHRA (acting on behalf of the Secretary of State).

Invoices are raised by the Finance Division of the MHRA and payment is required within 30 days.

The fee payable is reviewed annually.

Please note that a fee is payable for every blood bank within a trust. Where services are merged onto one central site it is important to advise us of this in writing so that we can ensure correct invoicing.

1.5 Confidentiality

Directive 2005/61/EC [5] traceability requirements and consequent UK legislation [7] also require that identifying information on donors and recipients should be recorded by blood establishments and by those to whom the blood or blood components may be delivered. However, this information is not required to be submitted to the MHRA as part of a notification or confirmation of a SAE or SAR. The link between any submitted report and the traceability records held by the reporting organisation will be made through a local incident reference number that you associate with your report and that you record on the report source section of the SABRE form. The local incident reference number can be any reference used to identify a report locally but must **not** be the patient ID number, NHS number, donation number, donor number or any other reference that can be linked directly to personal details.

Although SABRE provides a single starting point for reporting to both the MHRA and SHOT, the reporter is also able to choose to submit a report to only one organisation. Reports can be made in confidence i.e. a SHOT only report cannot be viewed by the MHRA. Similarly, the user must specify if MHRA reports are to be made available to SHOT for review.

Any personal data that has been supplied in your registration or in your submitted reports of adverse events or reactions will be held on our database and will be used in accordance with the **Data Protection Act** [8]. This could be for statistical analysis, management, planning or in the provision of services by the Agency. The MHRA will treat all personal information as confidential. Whilst details of reported events or reactions may be disclosed, personal identifying details of patients and/or reporters will not.

Since 01 January 2005 the **Freedom of Information Act** [9] obliged the MHRA to respond to requests for information which it holds and is recorded in any form, and creates a right of access to that information. The Agency will carefully consider its obligations to SABRE reporters under the Act prior to any release or non-release of information.

If you are concerned that, as a result of having disclosed information, you may be penalised by your employer or that your actions may lead to your dismissal you may wish to consider whether the provisions of **The Public Interest Disclosure Act ('PIDA')** [10] will protect your employment position.

PIDA protects workers who make a protected disclosure of information, concerning certain types of matters relating to their employment, from being dismissed or penalised by their employers as a result of the disclosure. The Act also has the effect of making confidentiality clauses unenforceable where there is a protected disclosure.

1.6 Reporting to SHOT (Serious Hazards Of Transfusion)

Reporting to SHOT remains voluntary, but is required for compliance with HSC/2007/001 'Better Blood Transfusion' - safe and appropriate use of blood [11] and is a standard for the NHS Litigation Authority – CNST Clinical Negligence Scheme for Trusts in England [12].

Active participation in SABRE and SHOT by all hospitals was recommended by the chief medical officer for England in his 2007 annual report. A number of blood safety initiatives depend on continuity of SHOT data for monitoring and evaluation and it is therefore important that reporters use the SABRE system to initiate a report to SHOT at the notification stage. Reporters should select either 'Share this report with SHOT' or select the 'SHOT only report' box. SABRE will then prompt the SHOT Dendrite database to create a record for you and to send you an automated email link to the database. You will then be asked to log in separately to the SHOT Dendrite system and complete their online form.

Please refer to the SHOT Dendrite database user manual for details of how and what to report to SHOT. Alternatively, contact the SHOT office on 0161 423 4208.

2 WHAT – legal definitions and guidance

2.1 Serious adverse reactions (SAR)

Definitions

All italicised quotes are from the UK legislation [7].

A serious adverse reaction (SAR) is:

*'an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is **fatal, life-threatening, disabling or incapacitating**, or which results in or prolongs hospitalisation or morbidity'*

'blood establishments and the person responsible for the management of a hospital blood bank shall notify the Secretary of State (Competent Authority) of any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components –

- (i) collected, tested, processed, stored or distributed by the blood establishment, or*
- (ii) issued for transfusion by the hospital blood bank'*

International Society of Blood Transfusion (ISBT) definitions, clinical and laboratory features of reaction types.

The table in Annex A reproduces the ISBT's internationally agreed definitions of the serious adverse reactions terms listed in annex II, part D (annual notification format for serious adverse reactions) of Directive 2005/61/EC [5]. The use of ISBT terms has been agreed by a working party of the EU Commission and aims to facilitate the comparison of the information sent to the Commission from all EU Competent Authorities.

2.2 Serious adverse events (SAE)

Definitions

All italicised quotes are from the UK legislation [7].

A serious adverse event (SAE) is:

'Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.'

Reporting requirements

'Blood establishments shall notify... any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the blood establishment which may have an influence on their quality and safety, and;

'the person responsible for the management of a hospital blood bank shall notify... any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the hospital blood bank which may have an influence on their quality and safety,'

Distribution

'the act of delivery of blood and blood components to other blood establishments , hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion'

The following terms, though used, are not defined in the Directive 2005/61/EC [5]. Reporters in the UK should be guided by the following definitions to help in determining the need to report an SAE.

'Collection' means the collection of whole blood or apheresis components from the donor.

'Testing' means the mandatory or discretionary testing of the donation by the blood establishment. It also includes tests done by the blood bank on processed components or the recipient sample to determine compatibility.

Note: for SABRE reporting the event category 'testing of donations' should only be used by blood establishments. For laboratory testing errors use the event category 'other'.

'Processing' means manipulation of the blood donation or other blood components for further manufacturing or subsequent administration to humans.

Note: for SABRE reporting the event category 'processing' should only be used by blood establishments. For laboratory processing errors use the event category 'other'.

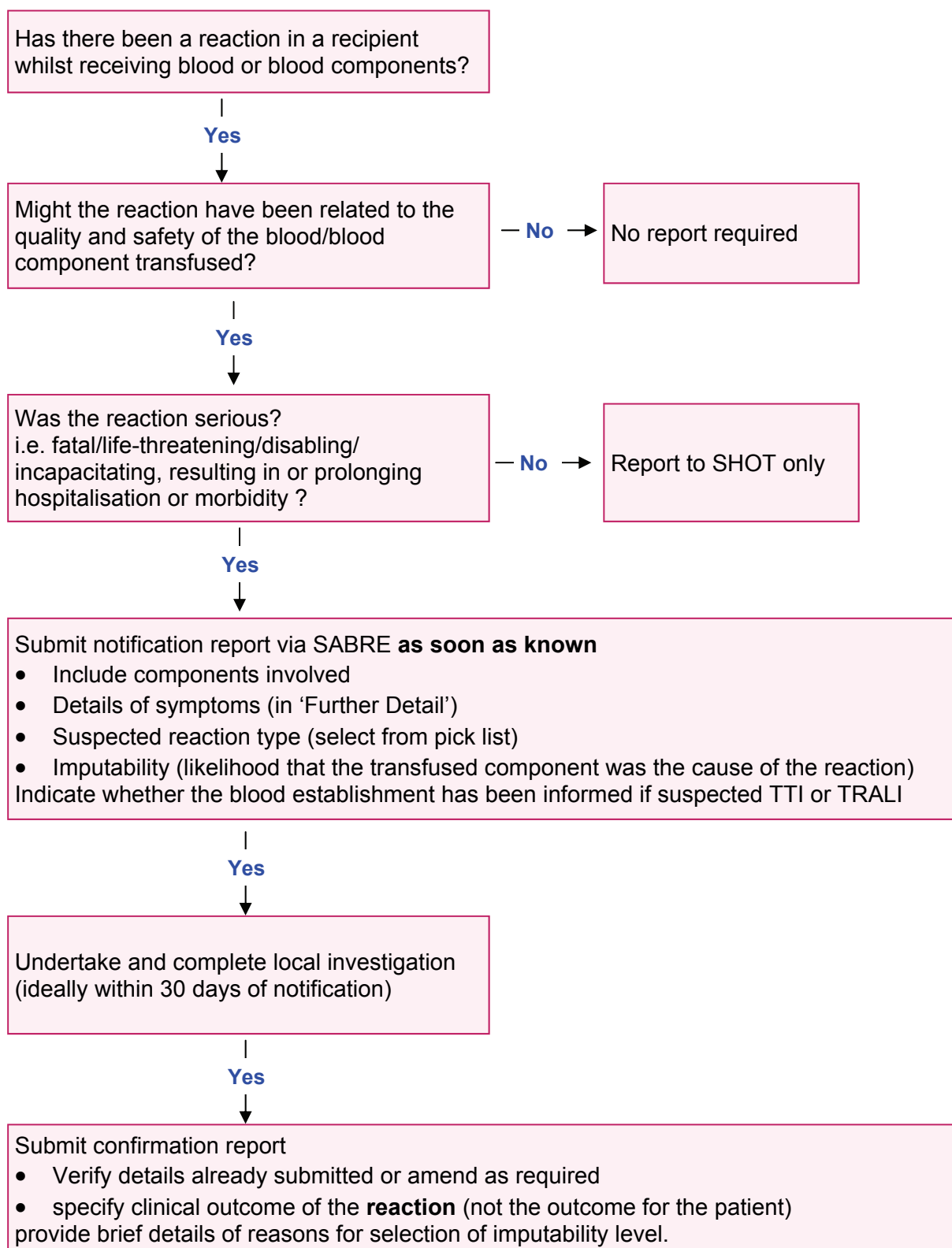
'Storage' means safe management of the blood at all stages of the cold chain and is undertaken by blood establishments and also by hospital transfusion laboratories. Blood leaves the control of the hospital transfusion laboratory at the point where it is issued for transfusion or transferred to a satellite refrigerator that is not within the control of the laboratory (it is arguable that all blood storage refrigerators should be within laboratory control).

EU Commission definitions of reportable SAEs

The table in Annex B [\[link\]](#) provides examples of serious adverse events and how they should be classified according to the proposed format in annex III, part C (Annual notification format for serious adverse events) of the Directive 2005/61/EC [5]. The use of these examples has been agreed by a working party of the EU Commission and aims to facilitate the comparison of the information sent to the Commission from all 28 Competent Authorities.

The table in Annex C provides some worked examples of what is and is not reportable to the MHRA as an SAE.

Figure 1 SABRE reporting flow chart for serious adverse reactions (SARs)



Note: Reports which are not confirmed and closed by the MHRA within 3 months of initial notification are likely to be referred to MHRA inspectors. If investigations are likely to take more than 3 months then please ensure this is indicated via a footnote.

Has there been an adverse event which occurred within the organisation's scope of responsibility as monitored by their quality management system?



3 HOW – using the SABRE online reporting system

SABRE can be accessed via the MHRA website: www.mhra.gov.uk. The system is secure and provides access only to registered users. Once registered, users have access to an electronic report form and to a workspace containing a library of their previously drafted and/or submitted reports. Draft reports can be edited online and may have electronic files (e.g. images, documents) attached for submission.

3.1 Help

Online help is available at every stage and every level when using SABRE. Not only does every page (registration, log in etc) and every section of the report form have general help text (accessed via a button at the top of the page), but each individual item on those pages has its own help information (accessed by clicking the help icon adjacent to that item).

Practical advice on the use of SABRE is available by email (sabre@mhra.gsi.gov.uk) or by telephone from the SABRE Helpdesk on 020 3080 7336.

3.2 Registration

Before using SABRE you must first register with the MHRA SABRE helpdesk. From your internet browser go to <http://www.mhra.gov.uk> and select the red 'SABRE – Report an adverse blood reaction/event' link on the right hand side of the screen.

Registration is a simple process requiring the completion of a straightforward online form on which you are asked to provide basic details of who you are, the name and type of organisation that you work for, and how we can contact you. In this and the other sections of the form, there are certain fields that you must complete prior to submission. These mandatory fields are marked with a red asterisk.

You are also asked to create and enter a password of your choice. This will be used each time you wish to log in to SABRE.

When you have completed the registration form, just click the 'submit' button to send your details to the SABRE helpdesk. A member of the SABRE team will then validate your request and send you an email containing your registration number. In certain circumstances staff on the helpdesk may wish to speak to you in person as part of the validation process.

The MHRA anticipates that many reporters will continue to operate as part of a haemovigilance team and may therefore choose to register using a shared email address. The MHRA recommends this approach. It will, however, still be possible for reporters to register individually. For obvious reasons of security and confidentiality, we recommend that you take care to ensure that your chosen password is carefully guarded within your team, but that it is accessible to more than one person so that reports can always be made as soon as possible even in the event of sickness or absence of the main reporter.

3.2.1 Updating registration details

You can change your password, email address, office address or telephone number. Simply log in to SABRE using your existing registration details and from your workspace click the 'Update Registration' button from the top navigation bar. Amend your details as necessary and submit.

If you change your email address, your original account will be temporarily suspended pending validation of the new one by the SABRE team. Until the account has been reactivated, you will not be able to log in using either your old details or your new ones.

3.3 Log in

Simply enter these three items and click 'LogIn'

- an email address (the one submitted on your registration request)
- a registration number (sent to you by the MHRA SABRE helpdesk)
- your password (chosen by you when registering).

If you have forgotten your password then please call the SABRE helpdesk to have it reset.

3.4 Workspace

After successfully logging in, your workspace will be displayed.

The workspace serves two primary functions:

- as a searchable library of all your draft and submitted reports
- as the platform from which you can
 - > create a new report
 - > open, read, and/or edit an existing report
 - > search the content of all draft and submitted reports and their attachments
 - > create folders so that you can organise and manage your reports.

On your first visit your workspace will be empty. Each time you save a draft or submit a report (whether a notification or a confirmation, an event or a reaction, or a SHOT only report) identifying details of that report will appear in the workspace.

Your workspace is **not** visible to the MHRA or SHOT.

The columns of summary information in the workspace are clearly labelled. The icons that will appear on the left hand side describe the type of report and its status. The icons contain the letters N, C or S.

N identifies a notification, C a confirmation, and S a SHOT only report.

The yellow background colour indicates the report's current status as draft, and the blue background indicates that you have submitted that report.

There are columns containing key identifying information from your notification and confirmation, and a separate column to indicate, where relevant, the date you requested a link to SHOT.

If you add a footnote to a submitted report, a letter F will also appear in that report's workspace record (see section 3.8 on footnotes).

3.4.1 Folder management

SABRE allows you to organise and store your reports in folders. You can create folders and sub-folders using the folder manager option that is available from your workspace. All folders are displayed alphabetically. You can name and rename folders and also delete them – although you cannot delete the reports they contain.

You do not have to use the SABRE folders facility but, as the number of reports in your workspace increases, you may find that it will help you organise your workspace and make it more manageable.

There is an online help text for this section that will guide you through the creation and management of folders. Further assistance can be obtained from the SABRE helpdesk.

3.4.2 Searching

SABRE incorporates an internal search facility that is accessible from the workspace. This allows you to search the content of all saved reports and questionnaires – whether they have been submitted or are still in draft form.

3.4.3 Printing

Each section within SABRE includes a button at the top of the screen that enables you to access a 'Printer Friendly Version' of your form should you need a hard copy for your local records.

If you encounter difficulties printing reports then this may be due to the version of Internet Explorer in use. We suggest you try using the File > Print option from your main tool bar or alternatively cut and paste the information into a separate Word document and then print that.

3.5 Report source

Much of this section of the report form will be pre-populated by SABRE with information submitted on your registration form.

The MHRA anticipates that many reporters will operate as part of a haemovigilance team and that you may therefore choose to register using a shared email address. The MHRA recognises that in those circumstances the person completing a report form may not be the registered SABRE user. For this reason the reporter name and email fields in this section remain editable, i.e. if you are not the person in whose name the registration was made, you can enter your own name and contact details. This will ensure that any communications from the MHRA or SHOT are directed to the correct person.

3.5.1 Local incident reporting

Your local incident reference number is also required in this section. This (coupled with the MHRA reference number assigned upon submission of your completed report form) is vital in avoiding potential confusion between incident reports. The local incident reference number can be any reference used to identify a report locally but must not be the patient ID number, NHS number, donor number or any other reference that can be linked directly to personal details.

The MHRA is very keen to ensure that reporting to SABRE does not interfere with, or replace, existing local reporting systems (e.g. local risk management reporting systems). To ensure that you are able to advise your colleagues promptly and clearly when you submit a report form, SABRE allows you to enter email addresses for report copies. Any email address correctly entered will receive an electronic copy of your report when you click submit. You may find this useful for ensuring that colleagues, including local risk managers, clinical governance leads etc, are kept aware of your reports of such events and reactions. If more than one email address is entered, each must be separated by a comma.

3.5.2 SHOT accessibility

You are also required to indicate whether you wish SHOT to have access to your report. MHRA recommends that you tick 'Yes'. You will then be sent an email link to the SHOT Dendrite database. However, please note that any additional details you submit in this report **cannot be viewed by MHRA**.

In circumstances where the incident observed is not reportable to MHRA (e.g. clinical errors where a patient was not harmed), you should report to SHOT Only. If you tick this box you will be sent a link to the SHOT Dendrite database only and **your report cannot be viewed by MHRA**.

3.5.3 Blood establishment notification

As well as indicating whether you have made a local report, you must also indicate whether you have submitted a report to the relevant blood establishment. This is of particular importance in TTI (transfusion transmitted infections) and TRALI (transfusion related acute lung injury) cases, or in any other circumstances where it is possible that the blood establishment will have to take prompt action to ensure the safety of blood or blood components that have been distributed elsewhere.

3.5.4 Reporting adverse incidents involving medical devices

Reporters are also reminded that adverse incidents involving failures or problems with medical devices (e.g. blood bags, syringes and needles, blood testing kits, refrigerated blood storage, blood salvage devices, irradiators, etc.) should also be reported to the MHRA Adverse Incident Centre – preferably using the appropriate [online system](#).

Further information on this aspect of incident reporting may be obtained from the Adverse Incident Centre (telephone: 020 3080 7080) or from guidance documents on adverse incident reporting available on the MHRA website: www.mhra.gov.uk

3.5.5 Reporting adverse incidents relating to a licensed medicinal product

The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines (CHM), and is used to collect information from health professionals and the general public on suspected side effects or adverse drug reactions (ADRs) to a medicine. Its continued success depends on the willingness of people to report suspected ADRs.

We collect Yellow Card reports from anyone in the UK on both licensed and unlicensed medicines including:

- prescription medicines
- blood products such as anti-D, IVIg and Octaplas
- vaccines
- over-the-counter (OTC) medicines
- herbal remedies
- swine flu antiviral medicines (Tamiflu or Relenza)
- swine flu vaccines (Pandemrix, made by GSK or Celvapan, made by Baxter).

The easiest and quickest way to report adverse drug reactions (ADRs) is to complete the electronic Yellow Card form on www.yellowcard.gov.uk. Full instructions for registering and completing the form are given on the website. You can keep track of all the Yellow Cards that you send and easily submit updated information if necessary. Alternatively Yellow Cards are also available:

- by downloading a pdf copy [from our website](#) to print out
- by writing to: MHRA, CHM Freepost SW2991, London SW8 5BR
- by emailing: pharmacovigilance@mhra.gsi.gov.uk
- from the [British National Formulary](#) (BNF)
- from the ABPI Medicines Compendium
- from the MIMS Companion.

3.6 Serious adverse reactions

3.6.1 Notification report

The first decision you have to make as a reporter is whether the incident you are reporting was serious i.e. was it associated with the collection or transfusion of blood or blood components and was it fatal, life-threatening, disabling or incapacitating, or did it result in or prolong hospitalisation or morbidity.

Then you need to decide if you are reporting a serious adverse event (SAR) or a serious adverse reaction (SAE) – and to tick the appropriate box. If you tick event, then only the event section will be accessible for completion.

Similarly, if you tick reaction, only that section will be available. This and the local reference number comprise the minimum information that must be entered before you can save a draft report.

If you ticked serious adverse reaction (SAR) on the report source section, SABRE will automatically allow you access to this section and the serious adverse event (SAE) section will not be available. Your report will automatically be submitted as a notification only report. If you already have all the information required to complete your report it is possible to change the report type to notification and confirmation and submit both at the same time.

Notifications of SARs should be submitted to the MHRA **as soon as possible**. Confirmations should be submitted as soon as possible after you have collated all the required information and your local investigation is complete. Where your report has been made available to SHOT, both the MHRA and SHOT recommend that you take appropriate account of the SHOT analysis of the incident when concluding your local investigation. The MHRA will send email reminders to reporters where a confirmation report has not been received within a reasonable time period. The time allowed will vary according to the nature of the reaction reported, but is generally one month.

Remember – SABRE allows you to save reports in draft whilst you collect the information required to complete all sections of the report form.

The SAR section has been designed by the MHRA primarily to collect only that data required by the EU haemovigilance system. In order to collect this data in a consistent manner suitable for summary analysis across Europe, standard picklists are provided for a number of areas. You will be required to choose from these lists when reporting:

- which blood component the serious adverse reaction is related to
- type of serious adverse reaction
- imputability level
- clinical outcome

Donors For serious adverse reactions of a donor, the blood establishment must notify the Competent Authority only where the quality and safety of the blood may be compromised.

3.6.2 Reaction types

These are:

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other allo-antibody
- Non-immunological haemolysis
- Transfusion-transmitted bacterial infection
- Anaphylaxis / hypersensitivity
- Transfusion related acute lung injury (TRALI)
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection, other (specify)
- Transfusion-transmitted parasitical infection (Malaria)
- Transfusion-transmitted parasitical infection, other (specify)
- Post-transfusion purpura
- Graft-versus host disease
- Other serious reaction(s) – specify (e.g. transfusion associated circulatory overload (TACO), transfusion associated dyspnoea (TAD), febrile non-haemolytic reactions (FNHTR) and uncategorised unintended responses)

NOTE: Please only select a reaction type from this list – listing symptoms is not appropriate in this field, but should be supplied under 'Further details' along with the results of any follow-up tests undertaken as part of the transfusion reaction investigation.

For ISBT definitions with clinical and laboratory features of reaction types please see Annex A.

3.6.3 Patient/donor information

Although some patient or donor information is required, this is only age and gender. Your local records will, of course, require further detail for fulfilling traceability requirements.

3.6.4 Confirmation report

When completing the confirmation section you must first indicate whether you are the person that submitted the Notification. If not, you will be asked to enter your own name and contact details.

Next you must indicate whether your original assessment was correct: i.e. which component type was implicated, whether there was a serious adverse reaction and whether that reaction was correctly described in the notification (and, if not, what the reaction actually was). You must also report the clinical outcome.

Please note that this relates only to the **clinical outcome of the reaction**. Deaths associated with a patient's underlying condition or any other cause should **not** be included. Therefore, if the eventual outcome for the patient is death **but** the cause of death is **not** due to the transfusion reaction, then the clinical outcome of the reaction is most likely to be either complete recovery, minor sequelae or serious sequelae – please select an option from the pick list.

Death should only be selected as a reporting option where the patient failed to recover from the transfusion reaction before dying. In these instances the imputability level will

assign the likelihood that the reaction can be attributed to the transfused blood or blood component.

If any associated components, products or reagents were required to be recalled and/or investigated as a result of the serious adverse reaction, the report should also include explicit reference to their fate and to any subsequent actions taken to ensure the future safety of the supply chain.

Lastly, a further assessment of the imputability level is required, as your assessment may have altered following review of the results of your local investigation. Where the final imputability level is 2 or 3, a report of your local investigation is required. Where the imputability level is considered to be ≤ 1 , it is useful to explain to what else the reaction could be attributed.

3.6.5 Imputability levels

Imputability means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process. The table below defines the imputability levels:

N/A	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components.
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
2	Likely	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

When you have completed the notification and/or confirmation sections and you are satisfied that all the information provided is both correct and complete, you should click Submit to send the Report to the MHRA.

3.7 Serious adverse events

3.7.1 Notification report

If you ticked serious adverse event (SAE) on the report source section, SABRE will automatically allow you access to this section and the serious adverse reaction (SAR) section will not be available. The system takes you directly to the notification only section but if you already have all the information required for both notification and confirmation you can change the report type in order to submit both at the same time.

Notifications of SAEs should be submitted to the MHRA **as soon as possible**. Consistently late submission of reports is an indicator of problems within the quality

management system and may prompt referral to the MHRA's Inspection, Enforcement and Standards Division.

Remember – SABRE allows you to save reports in draft whilst you collect the information required to complete all sections of the report form.

The SAE section has been designed by the MHRA primarily to collect only the data that are required by the EU haemovigilance system. In order to collect the data in a consistent manner suitable for summary analysis across Europe, standard pick-lists are provided for a number of areas. You will be required to choose from these lists when reporting:

- where within the system the serious adverse event occurred
- specification of the serious adverse event .

Clear definitions and explanations of all the terms used in this section of the form and in the pick lists are available in the SABRE online help text.

Annex B gives examples of serious adverse events and how they should be classified according to the proposed format in annex III, part C (annual notification format for serious adverse events) of Directive 2005/61/EC [5].

3.7.2 Event categorisation

Under the terms of Directive 2005/61/EC [5] the activities of hospital blood banks are limited to storage, distribution (to external satellite sites only) and other (serious failures of the quality management system). Sites which process blood and blood components (e.g. irradiation process) will need to be registered as blood establishments and may also report processing errors.

The clinical act of transfusion is outside the scope of the Directive 2005/61/EC [5] which applies only up to the issue of the blood component for transfusion. Therefore a serious adverse event occurring at the bedside before, during or after a transfusion (e.g. phlebotomy, administration of a blood component or use of an infected needle) is **not** reportable under the Directive 2005/61/EC [5].

Based on the above, an SAE concerning ABO or other blood group incompatibility should be reported only if it originates from: a mistake concerning blood or blood components exclusively for transfusion (i.e. **not** the intended recipient's blood sample collected by phlebotomy or finger sticks) **and** which occurred within the blood establishment or hospital blood bank.

SAEs that occur within the hospital blood bank scope of responsibility as monitored by their quality system (i.e. training of staff, security of equipment and premises, adherence to policies and procedures) should be reported when one or more of the following criteria apply:

- inappropriate blood/blood components have been issued/distributed for clinical use, even if not used
- the adverse event resulted in the loss of any irreplaceable autologous blood/blood component (e.g. rare blood group) or any highly matched (i.e. recipient specific) allogeneic blood/blood component
- the adverse event resulted in the loss of a significant quantity of unmatched blood or blood components
- the adverse event could have implications for other patients or donors because of shared practices, services, supplies or donors (i.e. repeated event inside or outside the BE/HBB)

- the adverse event could have a significant impact on the blood transfusion system e.g. by jeopardising the confidence of blood donors or recipients in the system.

Although there is a space for patient or donor information (age and gender) this is not mandatory as the blood or blood component involved may not have reached a patient. The MHRA does not need or want patient or donor identifying information (e.g. patient/hospital identification number or name) to be reported on SABRE.

3.7.3 Confirmation report

When completing the confirmation section you must first indicate whether you are the person that submitted the notification. If not, you will be asked to enter your own name and contact details.

Next you must indicate whether your original assessment was correct i.e. whether there was a serious adverse event and whether that event was correctly described in the notification (and, if not, what the event actually was).

3.7.4 Root causes

You must also provide what is described in the legislation as a 'root cause analysis'. What the MHRA requires here is simply details of the outcome of your local investigation into the SAE with evidence that as far as possible all root causes and contributory factors have been considered. This should help ensure that corrective and preventative measures are targeted effectively.

Serious adverse events are most frequently caused by human error. It is important that you do not report this as the root cause but investigate further into why the error was made e.g. distraction, recent process change, lack of knowledge/training, complexity of task etc.

3.7.5 Corrective measures

Finally, you are required to provide details of any corrective measures and preventative actions taken as a result of your investigation. Again you should provide information to explain what immediate action has been taken to deal with the serious adverse event **and** then explain what processes have subsequently been implemented to ensure that the situation does not recur; e.g. an expired unit of blood has been discovered, recalled and discarded **and** in future units due to expire at midnight will be held in the laboratory stock fridge and will only be issued up to 8 pm for immediate use.

3.7.6 Referral to the MHRA inspectors and the haemovigilance expert panel

Some reports may be referred to the MHRA Inspection, Enforcement and Standards division (IE&S) for further action where we are concerned that there may be a risk to patient safety e.g.

- death due to ABO incompatible transfusion
- multiple pre-transfusion testing errors
- recurrent failures of the quality management system/ineffective corrective and preventative actions
- late reports
- unusual recalls due to processing errors
- persistent issuing of wrong components.

Complex or unusual reports may be referred to the MHRA haemovigilance expert panel for their consideration and advice.

3.8 Footnotes

Once you have submitted a completed report form, the submitted sections are assigned read only status – you can review them but you cannot alter the content. If, however, you wish to submit some additional comments or information that cannot wait until the confirmation report is submitted, or if the confirmation report has already been submitted, then you may use the SABRE footnote facility. More than one footnote may be attached to a report. Attachments may also be made to footnotes.

3.8.1 Attaching files

Several parts of the report form are mandatory fields – you are required to enter information (by typing or ‘pasting’) or to choose from a pick list. However, the MHRA recognises that where you are asked for ‘further details’, for details of your local investigation, for information on any corrective action taken, or for an imputability report - it may be easier for you to attach a copy of an existing, locally produced, document.

At each stage of the reporting process, whether you are preparing a notification or a confirmation, SABRE allows you to attach a file to the form. This is done in the same way as you would attach a file to an email: you can browse through the files on your local system, and then click to attach the one you wish to submit. You may also add a descriptive comment to clarify the nature of the file.

3.9 Saving/submitting reports

When you have completed the notification and/or confirmation sections and you are satisfied that all the information provided is both correct and complete, you should click submit to send the report to the MHRA.

3.9.1 Acknowledgements and reference numbers

As soon as you submit your completed report form, SABRE will provide you with an electronic acknowledgement and an automatically generated, unique MHRA reference number. This number should be quoted in any correspondence or dialogue about your report, whether with the MHRA or with SHOT. The MHRA recommends that you cross-reference the MHRA reference number with your local records.

The reference number will appear in this format: 2010/011/008/HV1/001

It shows, from left to right, the year, month and day that the report is submitted. This is followed by an indicator that the report was submitted online via SABRE, and a sequential number for all reports submitted on that day.

The reference number is automatically entered onto the saved report form and onto the workspace listing, and is retained when a confirmation report is submitted. The same numbering system is used for SHOT only reports.

3.10 Logging out

It is important that you remember to log out after every session. Failing to log out may cause difficulties on the next occasion that you (or your colleagues) log in.

4 Additional information

4.1 Troubleshooting

Reports of serious adverse events and serious adverse reactions should only be submitted to the MHRA via SABRE.

Other means of submission should only be considered if SABRE is temporarily unavailable and the report is urgent. In such cases the MHRA Adverse Incident Centre should be contacted for guidance on how to report.

Enquiries, advice and feedback

MHRA

Tel: 020 3080 7336

email sabre@mhra.gsi.gov.uk

SHOT

Tel: 0161 423 4208 Fax: 0161 251 4395

email shot@nhsbt.nhs.uk

Annex A ISBT table of reportable serious adverse reactions (SARs)

Directive 2005/61/EC [5] categories	ISBT Definitions	
	Clinical features	Laboratory features
Immunological Haemolysis due to ABO incompatibility	Fever, chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypotension, pallor, jaundice, oligoanuria, diffuse bleeding, dark urine, decreased haemoglobin levels. Reactions may occur within 24 hours (acute) or may not manifest for up to 28 days (delayed)	Haemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels. Blood group serology shows ABO incompatible mismatch between recipient and donor.
Immunological Haemolysis due to other allo-antibody NOTE – Delayed serologic transfusion reactions (alloimmunisation) without clinical or laboratory signs of haemolysis are not reportable to SABRE.	As above.	As above but blood group serology shows either allo-antibodies to donor red cells or auto-antibodies in the recipient.
Non-immunological haemolysis	As above	As above but due to non-immunological, possibly mechanical factors such as malfunction of a pump or blood warmer, or the use of hypotonic solutions etc.
Transfusion-transmitted bacterial infection. Note – MUST be reported to the supplying Blood Establishment as soon as possible	Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.	Positive blood cultures from recipient and donor pack (matching organisms) or at least one component received by the infected recipient shown to contain the agent of infection.
Anaphylaxis/hypersensitivity NOTE – minor allergic reactions which respond quickly to symptomatic treatment like anti-histamine or steroid medications are NOT reportable to SABRE	Mucocutaneous signs and symptoms including urticaria, rash, pruritus, localised angioedema, oedema of lips, tongue, uvula and conjunctiva with airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). Respiratory symptoms may be laryngeal (throat tightness, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia) Usually occurs during or very shortly after transfusion.	Rising mast cell tryptase levels or IgA deficiency and/or anti-IgA in the recipient.
Transfusion related acute lung injury	Hypoxaemia ($\text{PaO}_2/\text{FiO}_2 < 300$ mm Hg or O_2 sats $< 90\%$ on room air), bilateral infiltrates on frontal chest X-ray, no evidence of TACO, no temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion. Usually acute onset.	Evidence of anti-HLA or anti-HNA antibodies in recipient with incompatibility between donor and recipient.
Transfusion-transmitted viral		Include if the recipient shows

infection (HBV)		evidence of infection post-transfusion and there was no evidence of infection prior to transfusion or any alternative source of the infection, PLUS either at least one component received by the infected recipient was shown to contain the agent of infection or at least one component received was donated by a donor who has evidence of the same transmissible infection.
Transfusion-transmitted viral infection (HCV)		As above
Transfusion-transmitted viral infection (HIV 1/2)		As above
Transfusion-transmitted viral infection - other		As above
Transfusion-transmitted parasitological infection (Malaria)		As above
Transfusion-transmitted parasitological infection – Other, specify NOTE: All suspected TTIs must be reported to the Blood Services as a matter of urgency.		As above
Post transfusion purpura	Bruising, severe haemorrhage, oozing wounds. Usually occurs 5-12 days post transfusion.	Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present.
Graft versus host disease	Fever, rash, liver dysfunction, diarrhoea. Usually occurs 1-6 weeks after transfusion.	Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism.
Other serious reaction(s) - specify	E.g. Febrile non haemolytic transfusion reactions (FNHTR) where fever $\geq 39^{\circ}\text{C}$ oral or equivalent and a change of $\geq 2^{\circ}\text{C}$ from pretransfusion value, chills, rigors, headache, nausea. Usually occurs within 4 hours of transfusion and without any evidence of haemolysis, bacterial contamination or underlying condition. E.g. Transfusion associated circulatory overload (TACO) – acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest x-ray, evidence of positive fluid balance. Usually occurs within 6 hours of completion of transfusion. E.g. Transfusion associated dyspnea (TAD) – respiratory distress occurring within 24 hours of transfusion but without the symptoms of TRALI, TACO or allergic reactions and not explained by any underlying condition.	

Annex B Table of reportable serious adverse events (SAE)

Serious adverse event, affecting quality and safety of blood component due to a deviation in:	Specification			
	Product defect	Equipment failure	Human error	Other (specify)
Definitions	Serious adverse event which is mainly linked to a defect of the blood or blood components. Product defect: blood or blood component which does not meet the quality and safety requirements set in annex V of the Directive 2004/33/EC [4], or which contain (remaining) contaminating agents despite screening, testing and processing having been undertaken properly (e.g.: product discarded after positive infection test result following a window period). Example: Clotting factor rates not compliant with specifications for fresh frozen plasma.	Serious adverse event which is mainly linked to a failure of the equipment. Equipment: any material used at any stage from the collection to the distribution of blood and blood components, such as whole blood collection machines, blood bags, aphaeresis kits and machines, production sets, reagents, test kits, bags for platelets or plasma storage, filters for leukocyte reduction, labelling machines, IT systems, etc. Note: Failures of the equipment – whether or not causing a Serious Adverse Event - should also be reported under the devices reporting procedure (e.g. pack check reveals a faulty seal and bag is discarded during processing: not a SAE but should be reported under the device reporting procedure).	Serious adverse event which is mainly linked to a human error. Human error: An inappropriate or undesirable human decision or behaviour that reduces, or has the potential for reducing, effectiveness, quality, safety, or system performance. It can be e.g. an omission: (forgetting to do something, or just leaving it out), a commission (performing an act incorrectly), a problem in sequence (right action, wrong order) or timing (too fast or too slow).	Any serious adverse event which cannot be classified in the already listed specifications.

Annex C To report or not to report – worked examples

* please note in the following examples, if a transfusion resulted in a serious transfusion reaction, these would be reported as SARs, regardless of whether it would have been an SAE or not.

	Event	Decision	Reasoning
a	4 units of red cells were sent in a validated storage container to a clinical area. The container has been validated for 4 hours. The blood was subsequently transfused to a patient 5 hours after the box was opened.	Not an SAE	Although the error relates to the storage of the components, the error occurred in the clinical area. These errors are not covered by the <i>Blood Safety and Quality Regulations</i> . However, since the process of sending blood to the clinical areas is controlled by the blood bank the local investigation should consider how this can be improved.
b	4 units of red cells were sent in a validated storage container to a clinical area. The container has been validated for 4 hours. The blood was subsequently transfused to a patient 5 hours after the box was opened. This error has been repeated a number of times.	Report as an SAE	The act of transfusing the blood inappropriately is still a clinical error and not reportable. However, the process of providing the blood to the clinical area is controlled by the blood bank. The process is not robust enough to prevent inappropriate components being transfused. Therefore the lack of a robust system is the adverse event. The adverse event is: associated with storage; was not highlighted by the QS at the time of the event; was discovered after the units had been issued; and might have led to harm.
c	4 units of red cells were sent in a validated storage container to a clinical area. The container has been validated for 4 hours, but the procedure had been modified so that the container should be returned after 2 hours. Despite a reminder from the blood bank to return the box after 4 hours, the blood was subsequently transfused to a patient 5 hours after the box was opened.	Not an SAE	The blood bank has carried out their procedure to the letter. The only error that has occurred is clinical.
d	4 units of red cells were sent in a validated storage container to a clinical area. The container had been validated for 4 hours, but the procedure had been modified so that the container should be returned after 2 hours. The blood bank did not remind the clinical area to return the blood and it was subsequently transfused to a patient 5 hours after the box was opened.	Report as an SAE	Again, the act of transfusing the inappropriate blood is not the reportable adverse event. The failure of the blood bank to carry out their procedure 'allowed' the inappropriate blood to be transfused, and this is the reportable adverse event. The adverse event is: associated with the storage; was not highlighted by the quality system; occurred after the blood was issued; and might have harmed the patient.

e	A sample was received in the blood bank with the patient's name misspelled (sample and request form mismatch), but this was discovered immediately and the sample was rejected.	Not an SAE	The blood bank quality system has highlighted a clinical error. The clinical error is not reportable.
f	A sample was received in the blood bank with the patient's name misspelled (sample and request form mismatch), but this was discovered when the components were being labelled.	Not an SAE	Although an adverse event occurred when the blood bank did not spot the incorrectly labelled sample, the result is that it is not a 'serious' adverse event. The adverse event: might result in the provision of inappropriate components for clinical use; was not highlighted at the time the adverse event occurred; was highlighted later on by the quality system; occurred before components were issued; is an isolated event, but because it was spotted before components were issued, would not have led to harm. In this example the adverse event is not serious and is not reportable to THE MHRA.
g	A sample was received in the blood bank with the patient's name misspelled (sample and request form mismatch), but this was discovered when the components were being labelled. This is the second occurrence within a month.	Not an SAE unless workload is small	The reasoning is similar to example f, above. However, it is not an isolated event. So, in this case a judgement needs to be made as to whether it is a repeated adverse event that shows a significant weakness in the quality system. Rather than concentrating on the absolute number of adverse events, consider it in relation to the volume of samples received in the blood bank. For a medium to large hospital with a medium to high workload only 2 errors may not demonstrate a significant and therefore, serious adverse event. This should therefore be reported and managed locally. In a small or private hospital where only tens of samples are processed in a week, the repeat error will be more significant and should be reported.
h	A sample was received in the blood bank with the patient's name misspelled on both form and sample. It was a new patient and the blood bank had no historical records. The error was not spotted at the bedside until after the first unit had been transfused.	Not an SAE	In this scenario, there are 2 clinical errors. Firstly, the sample was labelled incorrectly and secondly, the bedside check was not properly executed. Neither of these errors are reportable as serious adverse events. The blood bank has followed their procedures and has not made any error.
i	A sample was received in the blood bank with the patient's name misspelled (sample and request form mismatch). The error should have been spotted in the blood bank in accordance with the local sample acceptance protocol, but was not discovered until incorrectly labelled blood was at the bedside.	Report as an SAE	Although the error can be traced back to the clinical area, the reportable adverse event is the blood bank error of not spotting the incorrectly labelled sample which led to an inappropriate component being provided. The adverse event: might result in the provision of inappropriate components to the clinical area; was not highlighted at the time the error was made; was highlighted by chance (<i>i.e.</i> not by blood bank quality system); and might have harmed the patient.

j	Midwife administers anti-D in error to a patient who is Rh positive	Not an SAE (report to SHOT)	The incident involves a clinical error in administering a blood product. Clinical errors are not reportable and blood products are not covered by the <i>Blood Safety and Quality Regulations</i>
k	A laboratory transcription error has resulted in a pregnant woman's Rh group being recorded as Rh negative instead of Rh positive. As a result anti-D is issued in error and highlighted by the midwife.	Report as an SAE	The fact that the error has resulted in the issue of a blood product is irrelevant. In this case the adverse event is the blood bank incorrectly updating a patient record. The adverse event: might result in the provision on an inappropriate component (at another time); was not captured by the quality system at the time the error was made; was discovered by chance before a component was issued; and might have resulted in harm to a patient. In this scenario, even though the issue of Rh negative components to an Rh positive patient would not have caused harm, the potential for harm still exists if the same error had been made but <i>vice versa</i> .
l	A patient was admitted to A&E and was incorrectly linked to the patient record of a different person. A sample was taken and labelled with the incorrect details and sent to the blood bank. There were no historical records for this patient and blood was issued and transfused.	Not an SAE	This is a clinical/ administrative error and not covered by the <i>Blood Safety and Quality Regulations</i> .
m	A patient was admitted to A&E and was incorrectly linked to the patient record of a different person. A sample was taken and labelled with the incorrect details and sent to the blood bank. There were historical blood group records for this patient, but the blood bank failed to spot the blood group mismatch, ignored the warnings on the LIMS system and blood was issued and transfused. No transfusion reaction was occurred.	Report as an SAE	Similar to l, above, the initial error occurred in a clinical area. However, the blood bank has procedures in place to highlight these errors, but they were not acted upon. Failure to carry out the procedure of checking historical records is the adverse event. The adverse event: might result in the provision of inappropriate components for clinical use; was not highlighted by the quality system at the time of the event; was discovered after the issue of the components; and might have resulted in harm to a patient
n	A 2 unit crossmatch request was received in the laboratory for a patient with anaemia. The request form indicated no other clinical details or special requirements. This was a new patient and there were no historical records. Non-irradiated group specific units were electronically issued and transfused.	Not an SAE	This is a clinical error as they omitted to inform the laboratory that the patient had special requirements. Clinical errors are not covered by the <i>Blood Safety and Quality Regulations</i> .

	The laboratory was subsequently advised that this patient had lymphoma and required irradiated blood components.		
o	A 2 unit crossmatch request was received in the laboratory. The request form indicated that the patient had NHL and was being treated with Fludaribine, however no special requirements were indicated. The laboratory SOP states that all patients with these clinical details should have a serological crossmatch and be given irradiated blood components. Non-irradiated group specific units were electronically issued and transfused.	Report as an SAE	Although there has been a clinical/admin error in not completing the request form correctly, there has still been a failure of the QMS as the local SOP has not been followed. This led to an inappropriate component being issued and transfused. The adverse event: resulted in the provision of inappropriate components to the clinical area; was not highlighted at the time the error was made; was highlighted by chance (<i>i.e.</i> not by blood bank quality system); and might have harmed the patient.

References

- 1 Statutory Instrument 2005 No. 50 The Blood Safety and Quality Regulations 2005. ISBN 0 11 051622 2 <http://www.legislation.gov.uk/uksi/2005/50/contents/made>
- 2 Statutory Instrument 2005 No. 2898 The Blood Safety and Quality (Amendment) (No.2) Regulations 2005 ISBN 0 11 073494 7
<http://www.legislation.gov.uk/uksi/2005/2898/contents/made>
- 3 [Directive 2002/98/EC](#) of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. OJ, L 33, 08.02.2003, p30.
- 4 Commission [Directive 2004/33/EC](#) of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (Text with EEA relevance). OJ, L 91, 30.03.2004, p25.
- 5 [Commission Directive 2005/61/EC](#) of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events (Text with EEA relevance) OJ L 256 , 01/10/2005 P. 0032 – 0040.
- 6 Commission [Directive 2005/62/EC](#) of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments (Text with EEA relevance). OJ L 256 , 01/10/2005 P. 0041 - 0048
- 7 Statutory Instrument 2006 No. 2013 The Blood Safety and Quality (Amendment) Regulations 2006 <http://www.legislation.gov.uk/uksi/2006/2013/contents/made>
- 8 Data Protection Act 1998. ISBN 978-0105429982
<http://www.legislation.gov.uk/ukpga/1998/29/contents>
- 9 Freedom of Information Act 2000. ISBN 978-0105436003
<http://www.legislation.gov.uk/ukpga/2000/36/contents>
- 10 Public Interest Disclosure Act 1998.
<http://www.legislation.gov.uk/ukpga/1998/23/contents>
- 11 Department of Health. HSC 2007/001: Better blood transfusion - safe and appropriate use of blood.
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_080613
- 12 NHS Litigation Authority. Clinical Negligence Scheme for Trusts <http://www.nhs.uk>